REMARKS

General:

Claims 17-18, 27, 28, 31 and 32 were pending in the application. Claims 17-18, 27, 28, 31 and 32 stand rejected. Claims 17-18, 27, 28, 31 and 32 are canceled. Claims 33-57 are new.

Support for new claim 33 is found in original claims 1, 2, and 13. Support for a cardiac catheter is found at least at page 8, line 19. Support for a temperature sensing element to measure native blood temperature, as distinct from a temperature produced by the heat transfer device, is found at least at page 6, lines 6-15.

Support for new claims 34-57 is found at least in original claims 3-12, 14-24, and 27-28, respectively.

No new matter has been added.

35 U.S.C. § 102 rejections:

Claims 17 and 31 were rejected as anticipated by Sramek (US 4,836,214). Claims 17 and 31 are canceled, and these rejections are therefore moot.

Claim 27 was rejected as anticipated by Spencer (US 5,037,395). Claims 27 is canceled, and this rejection is therefore moot.

35 U.S.C. § 103 rejections:

Claims 18 and 32 were rejected as obvious over Sramek. Claims 18 and 32 are canceled, and these rejections are therefore moot.

Claim 28 was rejected as obvious over Spencer. Claims 28 is canceled, and this rejection is therefore moot.

35 U.S.C. §112 rejections:

Claims 17 and 18 were rejected as being indefinite, specifically for lack of antecedent basis. In light of the rejection of claims 17 and 18, these rejections are now moot.

New claims:

New claims 33-57 relate to a cardiac catheter comprising a heat transfer device including at least one temperature sensor wherein the heat transfer device is provided as a flexible film with at least one electrical resistor flow path and a temperature sensor element to measure the native blood temperature. It is respectfully submitted that the invention claimed in new claim 33 was searched in the original claims as provided in the preliminary amendment filed on February 26, 2002, in particular with respect to original claim 13. An embodiment of the device as claimed by new claim 33 is described at page 6, lines 6 to 15 wherein the said embodiment comprises a heat transfer device and a first temperature sensor to measure ambient blood temperature and a second sensor for measuring the temperature of the heat transfer device. Claim 33 is also similar to prior claim 17, although broader in scope and is presented in light of the Examiner's application of new art.

Neither Sramek nor Spencer discloses a temperature sensor, and claim 33 is believed to be both new and non-obvious over Sramek and Spencer.

In the interests of efficient examination and early allowance of claims 33-57, applicants offer the following observations on the prior art documents already of record in this application.

Quinn (US 6,387,052) discloses a catheter which measures cardiac flow using thermodilution. In the thermodilution method, heat is delivered to the blood via a heater and the temperature of the heated blood is measured down-stream from the heating element. The amount of heat taken up by the blood as it flows past the heater allows determination of the cardiac flow.

As Quinn requires the blood temperature post heating of the blood to be determined, the sensor provided by Quinn does not measure native or ambient blood temperature, but only heated blood. Claim 33 requires the claimed cardiac catheter to include a temperature sensing element to measure native blood temperature. Thus, claim 33 is novel over Quinn.

The catheter disclosed by Khalil (US 5,065,526) also uses the thermodilution method to determine cardiac output. As detailed above, in order to allow determination of cardiac flow via the thermodilution method, the temperature sensor provided on the catheter disclosed by Khalil must measure heated blood temperature and not native blood temperature. Thus, claim 33 is novel over Khalil.

Quinn et al (5,857,976), a divisional application of Quinn (US 6,387,052), again discloses a catheter which measures cardiac output using the thermodilution method. As detailed above the temperature sensor of such a catheter measures heated blood temperature and not native blood temperature. Claim 33 is, thus, novel over the teaching provided by this document.

Hughes (5,474,080) is also concerned with a measurement of cardiac output using the thermodilution method. In Hughes the blood is heated using a resistor heater provided on the catheter and the temperature of blood downstream (heated blood) (see column 4, line 38 - 41) is determined. Hughes does not provide a sensor to measure the native blood temperature as required by claim 33. Thus, claim 33 is novel over Hughes.

As discussed above, in order to determine cardiac flow by the thermodilution method wherein blood is heated and then the temperature of the heated blood is determined to calculate cardiac flow, each of the catheters disclosed by Quinn, Khalil and Hughes require a temperature sensor to determine heated blood temperature not native blood temperature.

None of these cited documents provide any teaching of methods to determine cardiac flow in which native blood temperature and not heated blood temperature may be measured. Further, none of these cited documents suggest any advantage of measuring native blood temperature.

There would be no motivation to modify the devices disclosed by these documents to provide a temperature sensing element to measure native blood temperature as measurement of native blood temperature and not heated blood temperature would render the devices disclosed by these documents unsuitable for their purpose as they would then not be able to determine cardiac output via the thermodilution method.

Thus, claim 33 is considered to be non-obvious over the teaching of these documents.

Al-Ali (US 5,509,424) and Nashef et al (US 5,682,899) disclose catheters for monitoring cardiac output wherein a heat transfer device is provided as a thermal coil of high resistance wire. There is no disclosure provided by either of these documents of providing a heat transfer device as a flexible film having at least one electrical resistor flow path as required by claim 33. Moreover, neither of these documents teach the provision of at least one temperature sensor to

monitor the temperature of the electrical flow paths and thus the temperature of the overall heat transfer. Thus, claim 33 is novel over these documents.

There is no suggestion or motivation in these documents to the skilled person to modify the heat transfer device disclosed therein to provide a heat transfer device as flexible film having at least one electrical resistor flow path as required by Claim 33. Furthermore, there is no suggestion of any advantage of modifying the heat transfer devices of these documents in this way.

The provision of at least one temperature sensor to monitor the temperature of the electrical flow paths, as illustrated in figure 3, and as required by claim 33, allows the temperature of the heat transfer device to be more accurately determined. This is particularly advantageous in the method used by the catheter of the present invention to measure cardiac flow, as in this method, only small amounts of heat are supplied to the heat transfer device. Neither Al-Ali nor Nashef provide any suggestion of the advantages of providing at least one temperature sensor on or within the heat transfer device to monitor the temperature of the electrical flow paths. Thus, claim 33 is non-obvious over these documents.

As the method utilized by Al-Ali and Nashef differs from those used by Quinn, Khalil or Hughes, the person skilled in the art would not consider combining the teachings of these documents. Thus, claim 33 is considered to be non-obvious over the teachings provided by a combination of these documents.

Abboud et al (US 6,562,030) does not disclose a cardiac catheter but a cryocather. The cryocatheter of Abboud does not include a temperature sensor to measure native blood temperature. Thus, as this document does not disclose all the features required by claim 33, claim 33 is novel over the teaching of this document.

As this document is not concerned with measuring cardiac output or measuring the temperature of blood, there would be no motivation to the skilled person to provide a temperature sensor to measure native blood temperature to provide a cardiac catheter as required by claim 33. Claim 33 is thus non-obvious over Abboud.

With respect to Morris (US 5,380,320), Champeau (US 6,208,881), Champeau (US 6,400,976), Dobak (US 2001/0037812), Griffin (US 6,144,870) and Saad (US 5,727,553), none

of these documents provide a temperature sensor to measure native blood temperature. As claim 33 requires this feature, claim 33 is novel over all of these documents.

Moreover, none of these documents teach or suggest any advantages of modifying a catheter including a heat transfer device to also include a temperature sensor to measure native blood temperature. Thus, claim 33 is believed to be non-obvious over these documents.

The cited documents, either alone or in combination do not teach or suggest a catheter as claimed by claim 33.

For all of the above reasons, the present invention, as claimed in claim 33, is considered to be novel and non-obvious.

As claim 1 is considered to be novel and non-obvious over the cited documents, Claims 34-57 are dependent from claim 33 and, without prejudice to their individual merits, are considered to be novel and non-obvious for at least the same reasons as claim 33.

Conclusion:

It is respectfully submitted that the application is in condition for allowance. A Notice of Allowance of all of claims 33-57 is solicited. If the Examiner believes, however, that direct communication would advance prosecution, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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BY: _____

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